Company Funding Arrangements – Host-based Sites

Scope

This policy applies to proposed company funding in all host-based HHMI laboratories. It does not apply to laboratories and shared research facilities at HHMI’s Janelia Research Campus.

Company funding includes any arrangement that would confer a financial benefit on the HHMI laboratory whether or not the funding is provided in exchange for access to or rights in the results of HHMI research. This can include direct financial support from companies in the form of a gift or sponsored research, as well as proposals from companies to provide equipment, services, or supplies, or significant discounts on purchases of goods or services, in exchange for access to or rights in research results. In addition, funding from a non-profit entity that is an affiliate of a for-profit company where the for-profit company receives access to or rights in the results of the funded research is treated as company funding and is subject to this policy.

Participation in a clinical trial (as that term is defined in HHMI’s Human Subjects Research-Host-based Sites policy) as a principal investigator or co-investigator is not covered by this policy. Instead, HHMI Investigator participation in clinical trials, including company-sponsored clinical trials, is subject to HHMI’s Human Subjects Research policy. For clarification, company funding of human subjects research in HHMI laboratories that is not a clinical trial is subject to both this policy and the Human Subjects Research policy and, as noted below, certain more restrictive terms in the Human Subjects Research policy will apply to this overlapping category of research.

Policy

In General

HHMI review is required for all company funding proposals. An HHMI host institution may accept funding from a company to support research in the laboratory of an HHMI Investigator if, after review, HHMI concludes that the requirements of this policy are satisfied. In addition, any company funding must be consistent with the policies of, and approved by, the Investigator’s host institution.

HHMI Requirements

Any company funding proposal must be consistent with HHMI’s mission as a tax-exempt medical research organization devoted to the promotion of human knowledge within the basic sciences, and its effective application for public good. Each proposal must be reviewed by HHMI in advance, and must satisfy the applicable HHMI requirements described in this policy before the host institution accepts funding for an HHMI laboratory under the arrangement. HHMI may object to a host
institution proceeding with a proposed funding arrangement if it concludes that the arrangement would not be consistent with HHMI’s mission or would not be in the best interests of HHMI.

Gifts from Companies

The terms of any proposal from a company to provide a gift to a host institution to support research in an HHMI laboratory must be reviewed by the HHMI attorney assigned to the host institution prior to acceptance by the host institution. In the case of gifts that meet the criteria in this policy for no-strings-attached gifts, no further requirements of this policy apply.

No-Strings-Attached Gifts

In order for a gift to be considered a no-strings-attached gift and exempt from the requirements of this policy (other than the review requirement), the gift, taking into account the facts and circumstances associated with the gift: (i) cannot grant the company directly or indirectly any interest in or rights to use any invention, including but not limited to inventions made in the performance of activities supported by the gift; (ii) cannot provide the company directly or indirectly with preferential access to the host institution’s technology licensing process; (iii) cannot provide the company directly or indirectly with access to the results of research supported by the gift except for results that the Investigator has disclosed to other members of the scientific community at large, whether by presentation at seminars, informal scientific discussions or other public dissemination (e.g., posting on a website); and (iv) cannot provide the company with rights to use the project or research results for promotional purposes.

Other Company Funding Arrangements

Any arrangements between host institutions and companies providing funding for research in an HHMI laboratory other than no-strings-attached gifts as described above must satisfy each of the following requirements:

- **Transparency.** The Investigator must confirm that all laboratory members, including postdocs, graduate students, and technicians, have been informed of the sponsored project and of research-related terms of the funding arrangement (for example, confidentiality, publication rights, ability to distribute published materials) that may affect them or their research. The host institution is responsible for ensuring that the application of the research-related terms is limited to the sponsored project and will not negatively impact other research conducted by the laboratory. In addition, the host institution must have a mechanism for laboratory members to raise concerns that may arise regarding the impact of the funding arrangement on them or their research and have procedures for resolving any such concerns.

- **Conflict of Interest Analysis.** For all company funding projects, Investigators must comply with any conflict of interest requirements imposed by their host institutions; host institutions are responsible for identifying and managing any conflicts of interest in connection with the host institution’s receipt of company funding to support research in an HHMI laboratory. HHMI host institutions must review
company funding proposals for HHMI laboratories at their sites under the same conflict of interest policies and principles that apply to other host faculty, and any company funding arrangement for an HHMI laboratory must be consistent with the applicable host institution’s, as well as HHMI’s, conflict of interest policies. In addition, the following special conflict of interest rules apply to any company funding proposal for an HHMI laboratory.

- An HHMI laboratory may not receive funding from a given company if the Investigator consults for that company or owns more than 5 percent of that company’s equity. In addition, in cases where an Investigator does not have a current relationship with a company (for example, through a consulting or licensing arrangement) and owns 5 percent or less of the company’s equity, HHMI will consider on a case-by-case basis whether to approve any proposal for the Investigator's laboratory to receive funding from the company if (i) the Investigator founded the company, or (ii) the company was formed around technology developed in the Investigator’s laboratory. A case-by-case analysis also applies if a company owning a majority interest of a company described in clause (i) or (ii) of the preceding sentence proposes to fund research in the Investigator’s laboratory.

- Any proposal to provide company funding for research in an HHMI laboratory that constitutes an “observational study” (as that term is defined in HHMI’s Human Subjects Research – Host-based Sites policy) must comply with the conflict of interest requirements in this company funding policy and with any more restrictive requirements in the Special Conflict of Interest Rules for Human Subjects Research set out in the Human Subjects Research policy.

- **Proper Identification of HHMI Investigator.** Each funding arrangement affecting an HHMI laboratory must properly reflect the nature of the Investigator’s relationship to HHMI. For example, a funding agreement that gives a company rights in inventions arising in an HHMI laboratory must specify that the Investigator is an employee of HHMI and assigns rights in inventions to HHMI, which in turn assigns rights in inventions to the host institution, subject to a retained research license for HHMI. Company funding cannot be used to provide any portion of the salary or benefits of any HHMI employee, including Investigators.

- **Project Specific.** Except in the case of no-strings-attached gifts and company-provided equipment, company funding for research in an HHMI laboratory must be designated for a specific project. Each funding arrangement for distinct projects within a lab must be separately approved by HHMI. HHMI does not permit non-project-specific company funding in its laboratories.

- **Path to Publication of Research Results.** The results of the project must be publishable on terms acceptable to the Investigator and the host institution, taking into account the nature of the research.

- **Sharing of Published Research Materials.** Any reagents or other research materials, data, and software that are integral to a publication of research results must be able to be shared with the academic research community following publication, consistent with HHMI’s Policy on Sharing Published Materials/Responsibilities of HHMI Authors. Accordingly, the parties to any agreement providing funding for an
HHMI laboratory must agree to make any of their materials, data and software that are integral to a publication available upon request (supplies permitting) on reasonable terms to scientists at nonprofit institutions so that others may validate the published results and extend them in new directions.

- **Freedom for Investigators to Pursue Research Objectives.** The agreement must allow the Investigator to terminate participation in the project on reasonable notice and to work alone or with academic collaborators in the research field after the Investigator's participation in the funded project concludes. Restrictions on research in the field with other companies, or with academic colleagues on projects funded by other companies, are permitted if acceptable to the Investigator and the host institution.

- **Limitation on Scope of Rights Granted to Company Sponsor.** The agreement cannot provide for assignment to the company of sole ownership of intellectual property developed in an HHMI laboratory. Any rights granted to the company sponsor in intellectual property developed by an HHMI laboratory (e.g., an option to negotiate for a license) must be limited to inventions or research results arising from the funded project and cannot include rights in research by an HHMI laboratory outside the scope of the funded project. This policy does not, however, preclude a host institution from granting rights in pre-existing intellectual property, so-called background intellectual property, to a company sponsor if such background intellectual property is used in the funded project and/or is necessary for the company to exercise the rights it is granted with respect to inventions or results arising from the funded project.

- **Indemnification for HHMI.** HHMI must be indemnified by the company for claims and liabilities arising from any commercial use of project inventions and research results to the same extent that HHMI requires in licenses by host institutions of inventions made in HHMI laboratories. HHMI must be indemnified by the company to the same extent as the host institution for any other types of claims and liabilities in connection with the funded research. HHMI is not a party to company funding agreements, but should be identified as a third party beneficiary, as appropriate.

**Procedures for Review of Company-sponsored Research Proposals**

**Host Institutions.** Host institutions should inform the HHMI attorney for the site when the host institution is considering entering into a company funding arrangement for an HHMI laboratory or providing company funding to an HHMI laboratory under a previously executed master agreement with a company. The host institution is responsible for negotiating the terms of company funding agreements based on the policies and procedures that apply to the host institution’s non-HHMI faculty, except as otherwise required by this policy.

HHMI is not a party to company funding agreements, just as HHMI is not a party to grant and other funding arrangements between host institutions and other sponsors. The host institution receives and administers all approved company funding. HHMI Investigators cannot sign company-sponsored research agreements as a party but may sign to indicate that they have read the agreement and acknowledge its terms.
Investigators. Investigators exploring opportunities for receiving company funding to support proposed research in their laboratory should complete the HHMI Company Funding Questionnaire on the HHMI Investigator Portal. The Investigator’s HHMI attorney and scientific officer will review the information and discuss the proposal with the Investigator as necessary to confirm that the proposed project is consistent with HHMI’s medical research mission and advances the Investigator’s research.

HHMI. The Investigator’s HHMI attorney will review an early draft of the proposed funding agreement and discuss its research-related terms with the Investigator and appropriate host institution personnel. The purpose of this early review is to provide the Investigator with a clear explanation of the research-related terms of the agreement (for example, confidentiality, publication rights, ability to distribute published materials, restrictions on future research) while allowing the Investigator and host institution to determine whether the terms, if otherwise consistent with this policy, are acceptable in the context of the particular project under consideration.

The Investigator’s HHMI attorney will review a final draft of any funding agreement for an HHMI laboratory, or the terms of any existing master agreement, as applicable, to confirm that the requirements of this policy are satisfied. The HHMI attorney will discuss the final agreement with the Investigator to confirm that the Investigator understands the implications of the agreement for the laboratory’s research. Following written confirmation from the Investigator that the Investigator has read, understands, and is satisfied with the terms of the agreement, HHMI will inform the host institution that HHMI does not object to the host institution proceeding with the arrangement.

Related Procedures, Forms and Policies

- Sharing Published Materials/Responsibilities of HHMI Authors
- Funding Arrangements with Nonprofit, Individual, and Governmental Sources - Host-based Sites
- Human Subjects Research
- Company Funding Questionnaire on the Investigator Portal

Contact

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